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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,854	01/17/2001	Samuel G. Armato III	200655US20	4576
22850	7590	03/29/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER BHATNAGAR, ANAND P	
			ART UNIT 2623	PAPER NUMBER

DATE MAILED: 03/29/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,854

Applicant(s)

ARMATO ET AL

Examiner

Anand Bhatnagar

Art Unit

2623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-7</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A.) Claims 1-7, 12, 14, 15, 18-24, 29, 31, 32, 35-41, 46, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (U.S. patent 5,881,124) and Vining (U.S. patent 6,272,366 B1).

Regarding claims 1, 18, and 35: Giger et al. discloses a method for the automated segmentation of lung regions in thoracic images (Giger et al.; fig. 1 and col. 1 lines 7-11) comprising:

acquiring image data representative of a cross-sectional thoracic image (Giger et al.; figs. 1 and 2A and col. 3 lines 66 and 67, and col. 4 lines 1-3);

segmenting the lung regions (Giger et al.; fig. 1 and col. 3 lines 55-58).

Giger et al. discloses to obtain a cross-sectional image of the thorax from which the lung boundaries are detected. Giger et al. does not teach to establish a seed in a major airway and to grow the seed and then extract the major airway. Vining teaches to grow seed and to grow the region of a selected organ in order to extract this specific organ as a region of interest, such as the tracheobronchial airways (Vining; fig. 15 and col. 3 lines 5-10, 23-30, and 54-56). It would have

been obvious to one skilled in the art to combine the teaching of Vining to that of Giger et al. because they are analogous in obtaining and processing images of anatomical structures to analyze these regions for presence of an pathological abnormality. One in the art would have been motivated to incorporate the teaching of Vining into the system of Giger et al. in order to have a reliable efficient method for examining the tracheobronchial and/or colon of a patient to detect early cancer (Vining; col. 2 lines 13-15).

Regarding claims 2, 19, and 36: The method further comprising:

determining a first pixel corresponding to a center of mass of the segmented major airway (Vining; col. 3 lines 23-30, wherein the seed point is planted inside the lumen of the organ. It is obvious to one skilled in the art for a dilation process in image processing using a seed point is usually performed wherein the seed point is placed in the center of the region of interest.).

Regarding claims 3, 20, and 37: The method further comprising:

centering, in a subsequent cross-sectional thoracic image, a search region over a second pixel corresponding to the first pixel; and

establishing, in the subsequent cross-sectional thoracic image, another seed point at a lowest density pixel within the search region.

Giger et al., as modified by Vining, discloses to analyze a plurality of computed tomographic images using a seed point. Giger et al. does not teach to center the subsequent image of a search region over a second pixel corresponding to the first pixel. It is obvious to one skilled in the art that once a

region of interest is picked in an image of a plurality of images that the same region in all subsequent images corresponding to the region of interest chosen in the first image is analyzed accordingly. The first image would contain the first pixels, the second image would contain the second pixels, the third image would contain the third pixels, etc. It is also obvious to one skilled in the art that placing the seed point is a matter of configuration in the process of image dilation (it can be placed on the pixel with lowest/highest intensity/density, on an edge/boundary/contour of an object, in the center/core of the object, etc.

Regarding claims 4, 21, and 38: The method wherein the major airway is the trachea (Vining; col. 3 lines 53-56). The obvious and motivation are the same as claim 1 above.

Regarding claims 5, 22, and 39. The method wherein the major airway is one of the first main stem bronchus and the second main stem bronchus (Vining; col. 3 lines 53-56). The obvious and motivation are the same as claim 1 above.

Regarding claims 6, 23, and 40: A method for the automated segmentation of lung regions in thoracic images (Giger et al.; fig. 1 and col. 1 lines 7-11), comprising:

generating at least one lung contour to segment the lung regions a cross-sectional thoracic image (Giger et al.; fig. 1 and col.3 lines 53-60 where the thorax and lung boundaries are detected).

Giger et al. discloses to obtain images of the thorax containing the lungs wherein a gray scale analysis is performed on the images in order to detect any

pathological abnormalities that may be present (col. 3 lines 53-63). Giger et al. obtains multiple computed tomographic images of the lungs. Giger does not disclose to analyze the images for specific anatomical locations in the images, such as the fusion of the lungs, the cleft point, the anterior junction line, etc. It would have been obvious to one skilled in the art to modify the system so that any number of anatomical points of the lungs (such as the cleft, the costophrenic angle, anterior junction line, the points where the lungs are fused together, etc.) as well as any neighboring anatomical structures (such as the diaphragm, heart, esophagus, etc.) may be analyzed using the gray scale of the images, taken into consideration into the data of the image, or suppressed/extracted from the image to enhance the region of interest in the images.

Regarding claims 7, 24, and 41: It is rejected for the same reason as claim 6, 23, and 40 above and for the following limitation of: identifying, within each row of pixels that includes a pixel of the line segment with the highest average gray level value, a pixel with the highest gray level within a predetermined distance of the line segment with the highest average gray level value; and

including within the anterior junction line the pixels identified as having the highest gray level in each row.

It is obvious to one skilled in the art that once the gray scale of all the images are obtained then this data can be analyzed for pixel intensities and their respective locations (the x-y positions, which is equivalent to the row and columns) in each image.

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Regarding claims 12, 14, 15, 29, 31, 32, 46, 48 and 49: They are rejected for the same reasons as claims 1, 18, and 35 and claims 6,23, and 40 combined.

Regarding claims 35-41, 46, 48, and 49: For the limitation of a computer readable medium (col. 12 lines 32-34).

B.) Claims 8-11, 13, 16, 17, 25-28, 30, 33, 34, 42-45, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armato et al. (WO 99/42031) in view of Giger et al. (U.S. patent 5,881,124).

Regarding claims 8-11, 13, 16, 17, 25-28, 30, 33, 34, 42-45, 47, 50, and 51: A method for the automated segmentation of lung regions in thoracic images, comprising:

Armato et al. discloses acquiring image data representative of a thoracic image (Armato et al.; page 4 bottom half of page, where the image of the Thorax is obtained and the lungs counters detected);
generating initial lung contours to segment the lung regions (Armato et al.; page 4 bottom half of page, where the image of the Thorax is obtained and the lungs counters detected);

refining the lung contours by applying a rolling ball filter to the initial lung contours to identify indentations along the initial lung contours (Armato et al.; fig. 1 elements S7 and S8, fig. 11, page 9 lines 1-6, and page 14 bottom of the page the description of Fig.11).

Armato et al. discloses to obtain images of the lungs and to smooth the contours in the image using a smoothing and a rolling ball filter. Armato et al. does not teach to obtain a cross-sectional image of the thorax nor teaches to determine the characteristics of the indentations and what causes the indentations, such as the diaphragm. Giger et al. teaches to obtain a cross-sectional image of a patient and detect the lungs in the image to analyze for any presence of an abnormality within the lungs (Giger et al.; fig. 1 and col. 3 lines 50-60). It would have been obvious to one skilled in the art to combine the teaching of Giger et al. to that of Armato et al. because they are analogous in imaging the lungs for detecting any presence of abnormalities. One in the art would have been motivated to incorporate the teaching of Giger et al. to that of Armato et al. in order to have a system to allow the various lesions to be detected, they must be analyzed at different threshold levels because they have different sizes and composition (Giger et al.; col. 2 lines 29-34).

As for the limitation of detecting the characteristics/geometrics of the holes/indentations and the cause of these holes/indentations: It would have been obvious to one skilled in the art to first analyze these features in order to know where the indentations are present, their respective sizes and which contours in the image contain these indentations such as the diaphragm so that the algorithm is only applied to these locations/contours, and if needed, the algorithm adjusted for the different sizes of indentations to make the system more efficient.

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Regarding claims 42-45, 47, 50 and 51: For the limitation of a computer readable medium (col. 12 lines 32-34).

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Clarke et al. (U.S. patent 5,987,094) for image enhancement of digital medical images.

Uppaluri et al. (U.S. patent 6,466,687) for CT imaging of pulmonary tissues to detect any abnormality.

Contact Information

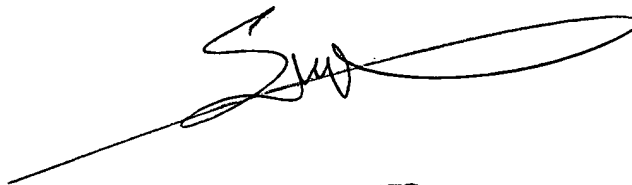
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand Bhatnagar whose telephone number is (703) 306-5914, whose supervisor is Amelia Au whose number is 703-308-6604, group fax is 703-872-9306, and Tech center 2600 customer service office number is 703-306-0377.

AB

Anand Bhatnagar

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March 16, 2004



**SAMIR AHMED
PRIMARY EXAMINER**